A/# PATENT
Docket No.: P-3818
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jc519 U.S. PTO 09/12/97

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION AND FEE TRANSMITTAL FORM

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of:

Inventor: Michael J. Iskra

For: **COLLECTION CONTAINER ASSEMBLY**

Enclosed are:

[X]	11	pages of specification
[X]	1	page of Abstract
[X]	4	pages of claims
[X]	3	sheets of drawing [X] formal [ ] informal
[X]	2	sheets of executed Declaration and Power of Attorney
[X]	2	sheets of executed Assignment
[X]	1	sheet of Recordation Form Cover Sheet (PTO-1595)

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EXPRESS MAIL CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this APPLICATION AND FEE TRANSMITTAL and the documents and fees referred to as enclosed therein are being deposited with the United States Postal Service on this date September 12, 1997 in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EM397666353USUS addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Rolando Melendez
(Typed or printed name of person mailing paper(s) or fee)

Rolando Melendez
(Signature of person mailing paper(s) or fee)

CALCULATION OF APPLICATION FEE

For	Number Filed			Number Extra		Rate	Basic Fee $770.00
Total Claims*	18	-20	=	0	x	$22.00	$0.00
Independent Claims	3	-3	=	0	x	$80.00	$0.00
Multiple Dependent Claims	[ ] Yes Additional Fee $260.00						
	[X] No Additional Fee						$0.00
						Total Filing Fee:	$770.00

*Includes all independent claims and all claims referred to in multiple dependent claims. See 37 C.F.R. §1.75(c).

[X] Please charge Deposit Account No. 02-1666 in the amount of $770.00 for the filing fee. Triplicate copies of this sheet are enclosed.

[X] The Commissioner is hereby authorized to charge any additional fees which may be required or credit any overpayment to Deposit Account No. 02-1666. Triplicate copies of this sheet are enclosed.

Respectfully submitted,

Dated: September 12, 1997

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COMBINED DECLARATION AND POWER OF ATTORNEY IN ORIGINAL APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

COLLECTION CONTAINER ASSEMBLY

the specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed: NONE

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application: NONE

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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FIRST INVENTOR'S SIGNATURE	DATE
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* Before signing this declaration each person signing must:
  1. Review the declaration and verify the correctness of all information therein; and
  2. Review the specification and the claims, including any amendments made to the claims.

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DATE OF DEPOSIT: SEPTEMBER 12, 1997

P-3818

UNITED STATES PATENT APPLICATION

OF: Michael J. Iskra

FOR: COLLECTION CONTAINER ASSEMBLY

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to a specimen collection container assembly and more particularly to a collection container for collecting biological fluid specimens where a small quantity of fluid may be collected and retained in the container while maintaining a container size sufficient to be easily accommodated and/or compatible with standard clinical equipment and instrumentation.

2. Description of Related Art

Blood samples and other biological fluid specimens are routinely taken and analyzed in hospital and clinical situations for various medical purposes. Collection, handling and testing of these samples typically requires the use of various medical testing instruments. As the blood and fluid specimens are usually collected in a standard sized collection tube, the medical instruments used to test the samples are designed to accommodate these standard sized collection tubes.

Conventional blood collection tubes used in most clinical situations are elongated cylindrical containers having one end closed by a semi-spherical or rounded portion and an opposed open end. The open end may be sealed by a

resilient cap or stopper. The tube defines a collection interior which collects and holds the blood sample. The most common size of these blood collection tubes are designed to accommodate approximately 10 ml of blood or other biological fluid samples. Illustrative of such blood collection tubes is the VACUTAINER® brand blood collection tube sold by Becton, Dickinson and Company, 1 Becton Drive, Franklin Lakes, NJ (registered trademark of Becton, Dickinson and Company).

A phlebotomist or other medical technician typically obtains a specimen of the patient's blood in the tube by techniques well known in the art. The tube is then appropriately labeled and transferred from the site of collection to a laboratory or other location where the contents of the tube are analyzed. During collection and analysis the tube may be supported by various medical instruments. The plasma or serum derived therefrom is processed and analyzed either manually, semi-automatically or automatically. In some cases, the specimen must first be dispensed from the collection tube to a sample test tube or cuvette.

In certain situations it is only necessary to obtain a small quantity of blood or other biological fluid specimens. These situations may include pediatric, or geriatric patients and other instances where large blood samples are not required. Small quantities of blood cannot be easily collected in standard collection tubes as described above because the sample level in such containers would not be adequate for retrieval prior to analysis. Such small quantities of fluids also have a tendency to significantly evaporate when stored in larger containers, thus concentrating the chemical and enzymatic constituents therein. This may result in erroneous analytical results and could possibly affect the diagnosis and treatment given to the patient. Therefore, it is desirable to employ small-volume containers which

substantially inhibit evaporation for the storage and delivery of minute fluid samples in the laboratory.

Although various fluid containers are available for this purpose, their small overall size and shape make it difficult for the phlebotomist or other medical technicians to handle and manipulate the tubes. Furthermore, such small dimension tubes are generally incompatible with most handling and testing instrumentation. For example, their use in conventional storage racks or those designed for loading into automatic chemical analyzers is substantially precluded because of their small dimensions. Certain automated chemical analyzers are capable of utilizing standardized conventional specimen containers as a means for introducing a patient's specimen into the analyzer. However, they are generally not equipped to handle specimen containers designed to hold small quantities of fluid. In addition, as the labels placed on most blood collection tubes are read by optical instrumentation such as bar code readers, conventional bar code labels may be too large to be supported on the small volume tubes.

Various specimen containers such as those incorporating a "false bottom" have been proposed to achieve decreased volume capacity in conjunction with standard external dimensions. However, these various specimen containers are not compatible with standard clinical equipment and instrumentation due to their design. In particular, these specimen containers have false bottoms with a generally flat, planar bottom end and a circular shaped opening.

In clinical use, it is desirable for such specimen collection containers to have rounded bottom configurations that closely simulate a standard-sized blood

collection tube configuration instead of planar bottoms. Rounded bottom configurations facilitate compatibility with clinical equipment and instrumentation.

Therefore there is a need to provide a specimen collection container assembly for collecting blood samples and other biological fluid specimens of relatively small volumes where the assembly may be accommodated and/or compatible with standard clinical equipment and/or instrumentation and where the integrity of the sample and specimens are maintained during storage and transport.

SUMMARY OF THE INVENTION

The present invention is a collection assembly comprising a container. The container preferably comprises an open top portion, a lower bottom portion and a sidewall extending from the open top portion to the lower bottom portion. Lower bottom portion comprises a closed bottom end or true bottom and an annular skirt extending from the closed bottom end to a rounded stop end. The annular skirt provides a false bottom effect to the assembly and the rounded stop end provides a means for allowing the container to be compatible with standard clinical equipment and instrumentation.

The true end may be the same or different material than the container and may be integral with the container or may be a discrete member. Additionally, the true end may be arcuate in shape to provide an internal volume for specimen collection having at least a partially rounded true bottom portion, or may be conical in shape.

Alternatively, the annular skirt may extend from the closed bottom end to a fully rounded second closed bottom end and may further comprise a cap or a stopper.

Preferably, the external dimensions of the container are about the same as a standard-sized or full draw blood collection container assembly. A standard-sized blood collection container assembly has an outer diameter of about 13 to about 16 millimeters, a length of about 75 to about 100 millimeters and an internal volume of about 6 to about 10 milliliters.

Most preferably, the assembly of the present invention can be either evacuated or non-evacuated. Desirably, the assembly is made from thermoplastic polymers. Most desirably, the assembly is made from polyethylene terephthalate, polypropylene, polyethylene, polyethylene napthalate or copolymers thereof.

An advantage of the assembly of the present invention is that it provides a full-draw blood collection container assembly having a reduced internal volume but with external dimensions about the same as a standard-sized blood collection container assembly.

A further advantage of the assembly of the present invention is that it provides a specimen collection container which is universally compatible with various clinical equipment and instrumentation. In particular, the assembly of the present invention does not require any external adapters and the like to be attached to the assembly to be compatible with various clinical equipment and instrumentation.

The assembly of the present invention may be easily handled by equipment configured to handle standard-sized blood collection tubes having standard external dimensions.

Most notably, is that the assembly of the present invention provides a blood collection container having full draw external dimensions but with a reduced internal volume as compared to standard-sized full draw blood collection tubes.

The assembly of the present invention therefore addresses the need for a full-draw size low-volume blood collection container assembly that presents the external dimensions of a standard-sized blood collection tube.

The assembly of the present invention may be used to reliably collect small samples of blood or biological fluids and to maintain the integrity of the samples during storage and transport as compared to using standard-sized blood collection tubes. In addition, the assembly of the present invention can also be accommodated by standard-sized blood collection, transportation, storage, and diagnostic equipment.

Most notably, is that the assembly of the present invention provides a rounded bottom configuration that closely simulates a standard-sized blood collection tube with a fully rounded bottom. This particular feature in conjunction with all of the features of the container, distinguishes it from the specimen containers that have flat planar bottoms.

The assembly of the present invention is also compatible with existing instrumentation, labels, and bar code readers and obviates the need for new

instrumentation and handling devices or procedures that would be required for smaller or varying sized tubes or tubes with flat planar bottoms.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a false bottom specimen tube of the prior art.

FIG. 2 is a longitudinal sectional view of the tube of FIG. 1 taken along line 2-2 thereof.

FIG. 3 is a perspective view of the assembly of the present invention.

FIG. 4 is a longitudinal sectional view of the assembly of FIG. 3 taken along line 4-4 thereof.

FIG. 5 is a perspective view of an alternate embodiment of the present invention.

FIG. 6 is perspective view of an alternate embodiment of the present invention.

DETAILED DESCRIPTION

The present invention may be embodied in other specific forms and is not limited to any specific embodiment described in detail which is merely exemplary. Various other modifications will be apparent to and readily made by those skilled in

the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 and 2 show a false bottom specimen container **10** of the prior art, having a sidewall **12** having an outer surface **14** and inner surface **16**. Sidewall **12** extends from upper portion **18** to lower portion **20**. Upper portion **18** includes an open end **22** and a rim **24**. Lower portion **20** comprises a closed bottom end **26**. An annular skirt **28** extends from lower portion **20** and outer surface **14** to a flat planar bottom end **30** to define a false bottom **32**. Interior volume **34** extends between rim **24** and closed bottom end **26**.

Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 3 and 4 show the preferred embodiment of the present invention, assembly **50**. Assembly **50** is false bottom specimen container, having a sidewall **62** having an outer surface **64** and inner surface **66**. Sidewall **62** extends from upper portion **68** to lower portion **70**. Upper portion **68** includes an open end **72** and a rim **74**. Lower portion **70** comprises a closed bottom end or true bottom **76**. An annular skirt **78** extends from lower portion **70** and outer surface **64** to a rounded open bottom end or false bottom end **80** to define an open false bottom area **82**. Interior volume **84** extends between rim **74** and closed bottom end **76**.

Closed bottom end **76** may be positioned at any point below rim **74** thus providing a variable interior volume **84**. Closed bottom end **76** may be generally flat or planar in shape to provide a flat bottom surface for interior volume **84.** Alternatively, closed bottom end **76** may be arcuate in shape to provide at least a

partially rounded bottom surface for interior volume **84**. Most preferably, closed bottom end is generally conical in shape to provide a conical, pointed bottom surface for interior volume **84**. Additionally, closed bottom end **76** may be integral with sidewall **62** or may be a discrete member. Preferably closed bottom end **76** is integrally formed with sidewall **62**.

Rounded open bottom end **80** includes arcuate shoulder **86**. Arcuate shoulder **86** provides the assembly with a curved arcuate, or at least a partially rounded false bottom end **80**. The false bottom end provides for better compatibility with clinical equipment and analytical or diagnostic testing equipment or instruments which are designed to accommodate conventional standard-sized round bottom blood collection tubes.

Container **50** has an outer diameter **A** of about 13 millimeters, a length **B** of about 75 millimeters, as measured from rim **74** to arcuate shoulder **86** of rounded open bottom end **80**, and an interior volume **84** of about 1 to 3 milliliters. It is within the purview of this invention that container **50** may have an outer diameter of about 13 to about 16 millimeters, a length of about 75 to about 100 millimeters and an interior volume of about 1 to about 3 milliliters.

The invention, as shown in FIG. 5 includes many components which are substantially identical to the components of FIGS. 3-4. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 3-4, except that a suffix "a" will be used to identify the similar components in FIGS. 5.

As illustrated in FIG. 5, a further embodiment of the invention is assembly **100**, wherein annular skirt **78a** extends from closed bottom end **76a** and outer surface **74a** to a rounded closed bottom end or false bottom **120**. Rounded closed bottom end **120** is essentially a rounded or semi-spherical shape. Assembly **100** with the rounded closed bottom end or false bottom end is compatible with clinical equipment or instruments which are designed to accommodate conventional standard-sized round bottom blood collection tubes.

The invention, as shown in FIG. 6 includes many components which are substantially identical to the components of FIGS. 3-4. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 3-4, except that a suffix "b" will be used to identify the similar components in FIG. 6.

As illustrated in FIG. 6, a further embodiment of the invention is assembly **160** which includes a cap **180**.

The embodiment of FIG. 6 may be evacuated or non-evacuated. When assembly **160** is evacuated, it has a full-draw internal pressure so as to be able to draw a sufficient quantity of blood to substantially fill interior volume **84b**. Interior volume **84b** is typically maintained at a lower-than-atmospheric internal pressure so that when a blood collection probe penetrates through the cap placing interior volume **84b** in communication with the circulatory system of a patient, the lower-than-atmospheric pressure of interior volume **84b** will draw blood from the patient into the tube. Assembly **160** may be described as a full-draw blood collection tube because the internal pressure of interior volume **84b** is low enough to draw a volume of blood substantially equal to the volume of interior volume **84b**.

The various embodiments of the present invention may be manufactured by known manufacturing methods including but not limited to injection molding or according to the following method:

a. providing an elongated tubular housing having opposed first and second ends and a cylindrical wall therebetween which defines a tubular interior;

b. positioning a solid partition within the tubular housing between the first and second ends;

c. heating a forming tool or die that may be constructed of metal or durable conductive material to about 40°C to about 125°C and most preferably at about 70°C;

d. inserting one of the ends of the tubular housing into the forming tool that has an arcuate shaped recess such as spherical;

e. applying a force of about 25 to about 400 pounds per tube for about 3 to about 7 seconds to the tubular housing to cause the end to soften and to conform or assume the arcuate shaped recess of the forming tool; and

f. removing the tubular housing from the forming tool and cooling at about 70°F for about 10 seconds.

WHAT IS CLAIMED IS:

1. A collection container assembly comprising:

an elongate tubular housing having opposed first and second ends and a cylindrical wall therebetween defining a tubular interior; and

a solid partition positioned within said housing between said first and second ends;

said housing defining a volume for specimen collection therein between said first end and said partition,

said second end being reconfigured into at least a partially arcuate shape to provide said specimen collection tube with at least a partially rounded end.

2. The assembly of Claim 1, wherein said second end is open to an interior portion of said housing.

3. The assembly of Claim 1, wherein said second end is closed to define a fully rounded end.

4. The assembly of Claim 1, wherein said partition is integral with said housing.

5. The assembly of Claim 1, wherein said partition is arcuate in shape to provide said volume for specimen collection with at least a partially rounded bottom portion.

6. The assembly of Claim 1, wherein said partition is conical in shape.

7. The assembly of Claim 1, wherein said housing is a thermoplastic polymer.

8. The assembly of Claim 7, wherein said thermoplastic polymer is polyethylene terephthalate, polypropylene, polyethylene napthalate, polyvinyl chloride or copolymers thereof.

9. The assembly of Claim 1, wherein said housing comprises an outer diameter, a length and an internal volume, wherein said outer diameter is about 13 to about 16 millimeters, said length is about 75 to about 100 millimeters and said internal volume is about 1 to about 3 milliliters.

10. A method of providing a collection container assembly with an arcuate shaped end comprising:

providing an elongate tubular housing having opposed first and second ends and a cylindrical wall therebetween defining a tubular interior;

providing a solid partition within said housing between said first and second ends; and

reconfiguring one of said ends into at least a partially arcuate shape.

11. The method of Claim 10, wherein said housing is a thermoplastic polymer.

12. The method of Claim 11, wherein said thermoplastic polymer is polyethylene terephthalate, polypropylene, polyethylene napthalate, polyvinyl chloride or copolymers thereof.

13. The method of Claim 11, wherein said reconfiguring step further includes

inserting one of said ends into a forming tool having an arcuate shaped recess; and applying a force to said housing to cause said one of said ends to conform to the shape of said arcuate shaped recess.

14. The method of Claim 13, wherein said forming tool is heated prior to inserting one of said ends therein.

15. The method of Claim 14, wherein said forming tool is heated to a temperature of about 40°C to about 125°C.

16. The method of Claim 11, wherein said force is applied at a pressure of about 25 to about 400 pounds per tube.

17. The method of Claim 11, wherein said force is applied for a period of about 3 to about 7 seconds.

18. The method of providing a collection container assembly with an arcuate shaped end comprising:

forming an elongate tubular housing having opposed first and second ends and a cylindrical wall therebetween defining a tubular interior;

positioning a solid partition within said housing between said first and second ends;

inserting one of said ends into a heated forming tool having an arcuate shaped recess; and

applying a force to said housing to cause said one of said ends to conform to the shape of said arcuate shaped recess.

COLLECTION CONTAINER ASSEMBLY

ABSTRACT OF THE DISCLOSURE

The present invention is a collection container assembly comprising a container with a false bottom having a rounded open end and wherein the external dimensions of the container are substantially the same as a standard-sized blood collection tube but with a reduced internal volume.

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FIG-1

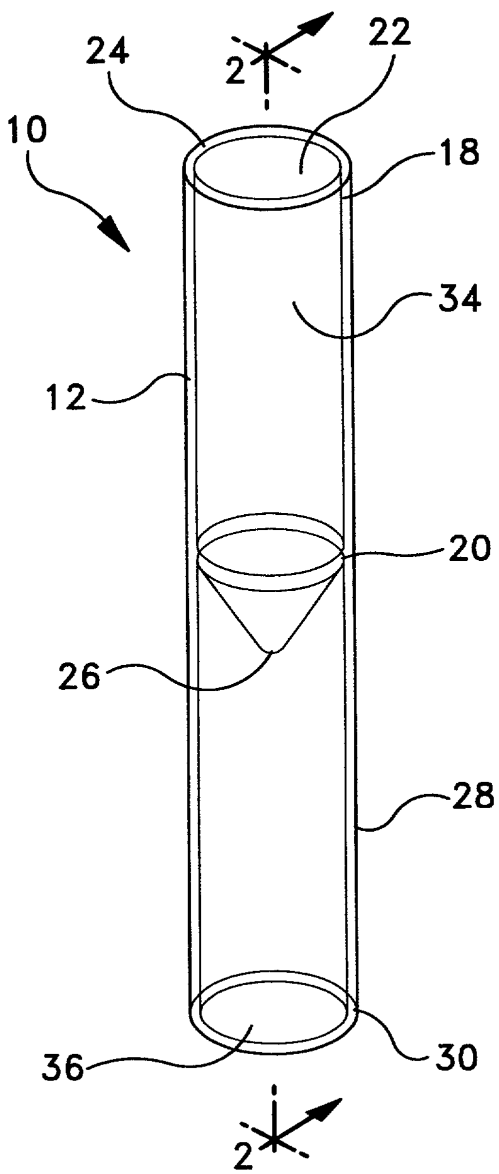


FIG-2

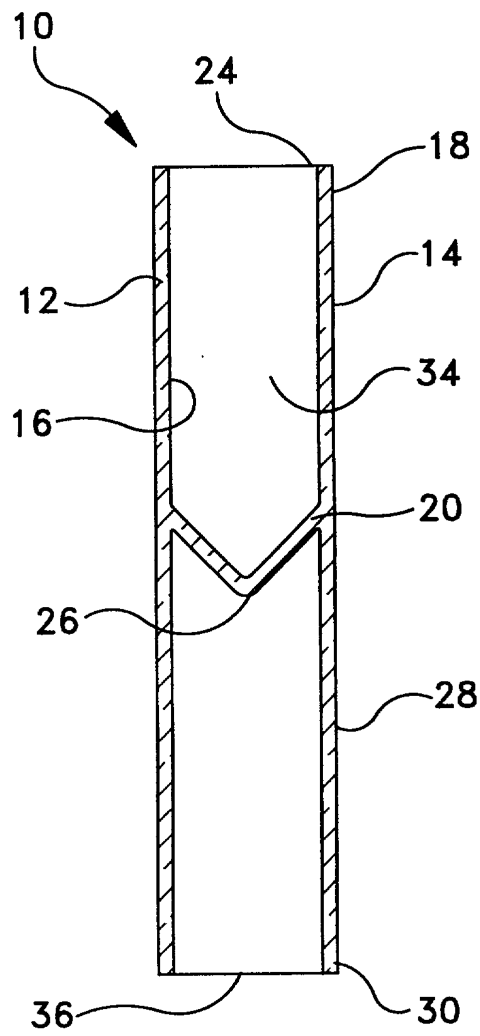
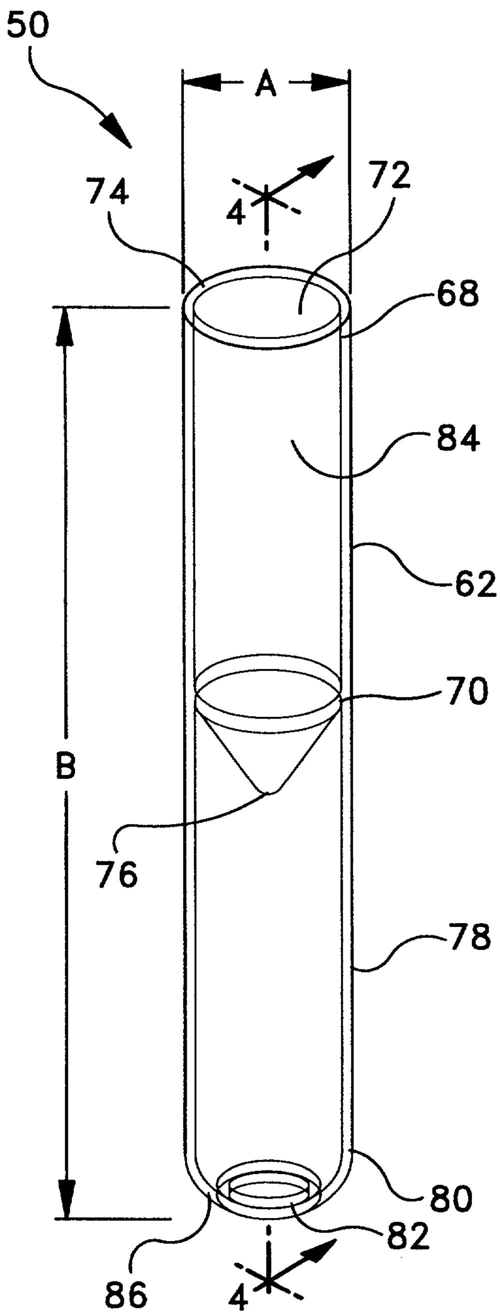


FIG-3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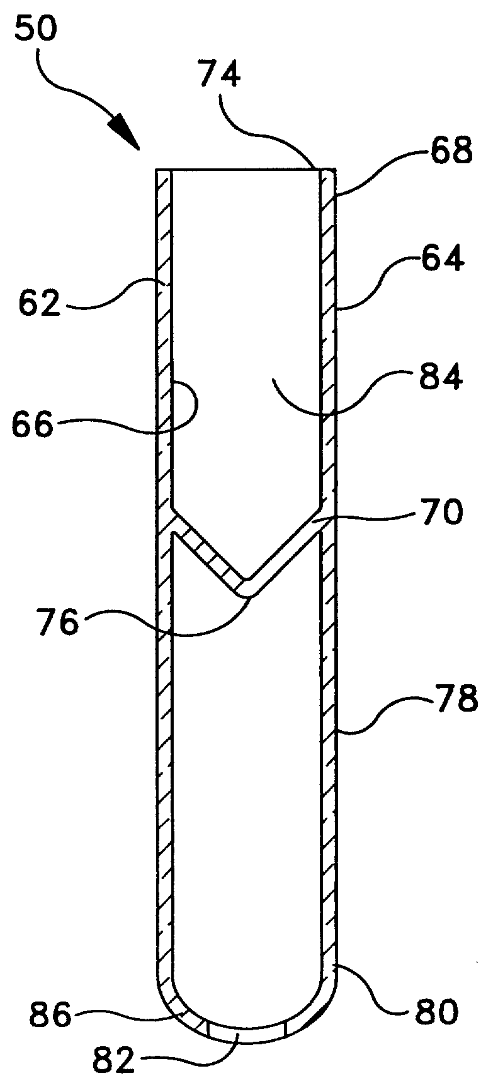
86
4

FIG-4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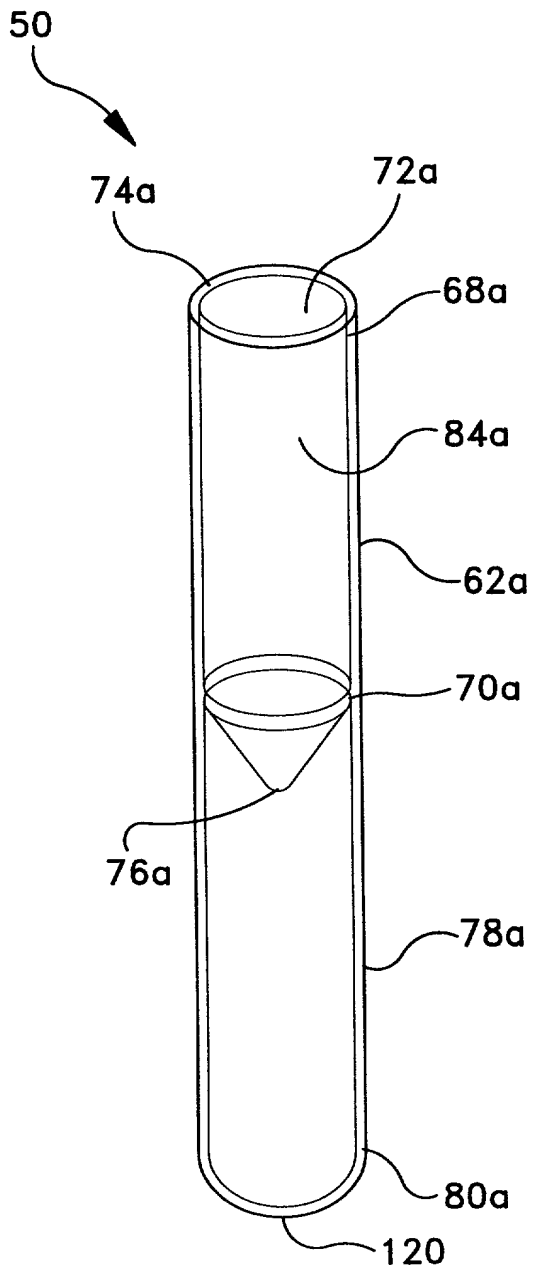
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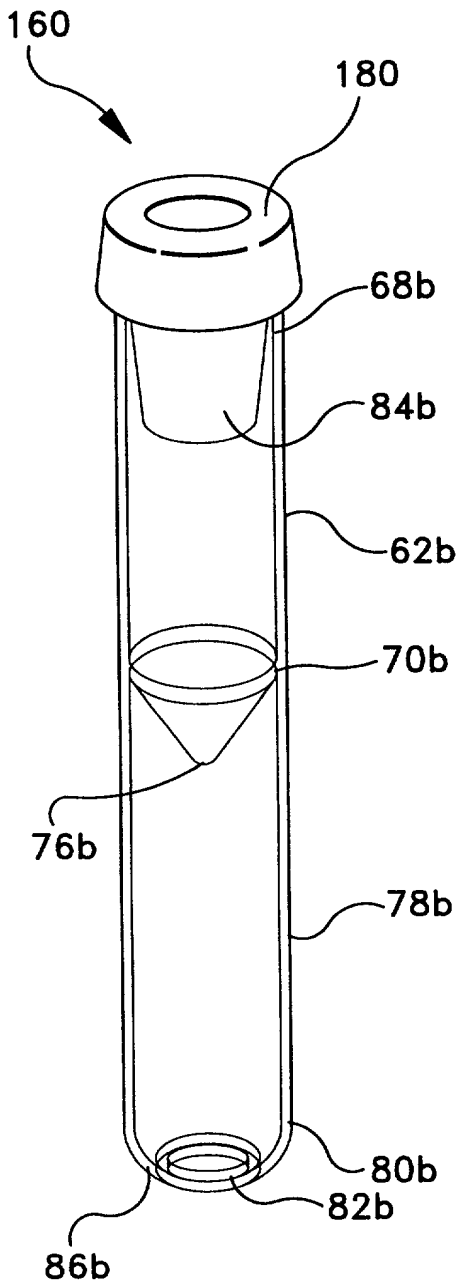
120

FIG-6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